REMARKS

The Office action mailed November 2, 2006 has been received and reviewed. All claims currently under consideration were rejected. The application is to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

A. Personal Interview

Applicants would like to thank the Examiner for the courtesy extended to the inventor N. Sandor Racz and applicants' undersigned representative during the personal interview of December 12, 2006. During the interview, the invention and outstanding rejections were discussed. Particularly discussed was the "flexible needle slidably mounted on a portion of the support needle" of, for example, applicants' instant independent claim 1, especially in comparison to the "sharp, hollow introducer component" of U.S. Patent 6,558,353 to Zohmann ("Zohmann") "used to puncture the skin". (Zohmann, column 4, lines 24-26). A commercial embodiment of the Zohmann device as well as a prototype of applicants' flexible spinal needle were displayed.

Furthermore, as identified by the Examiner,

> Applicant described his invention and the differences between his invention and the prior art (Zohmann). Replacement drawings were filed 04/05/04. The trademark name in the claim language is to be amended by applicant. Applicant proposed some claim language and the Examiner suggested he file formally [in order] for the amendments to be considered.

Applicants believe that the foregoing summaries, taken in view of the comments and amendments made herein adequately detail the interview. If, however, the Office believes more comment is necessary or desirable, then the Examiner is kindly requested to contact applicants' undersigned attorney, and further detail will be promptly provided.

B. Drawings

The drawings were objected to as being informal. As discussed at the interview and acknowledged in the Examiner Interview Summary, replacement drawings were earlier filed. (*See, e.g.*, US 2005/0090801 A1 which has formal drawings).

C. Specification

The Specification was objected to for informalities. For instance, reference numerals 34 and 37 were not thought to be disclosed in the Specification, and on page 9, paragraph 32, lines 8, tab 34 should be 32 as shown in FIG. 1.

With respect to reference numeral 34, it (*i.e.*, "an attach structure 34") is referenced in paragraph **[0035]**.

With respect to reference numeral 37, it (*i.e.*, "thread structure 37") is referenced in paragraph **[0040]**.

Paragraph **[0032]** has been amended as suggested by the Examiner.

D. 35 U.S.C. § 112, 2nd ¶

Claims 5 and 21 were rejected for applicants' use of the terminology "LUER-LOCK®". During the interview, the Examiner suggested the terminology "luer lock", which suggestion applicants have adopted by amending claims 5 and 21 accordingly. In view of the amendment, applicants request that the rejection be withdrawn.

E. 35 U.S.C. § 102

Claims 1-4, 6, 8-9, 12, 14-18, 20, 23, and 25 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Zohmann. Applicants respectfully traverse the rejection.

It was thought that

> "Zohmann discloses a spinal catheter assembly having a needle 50 and [an introducer] 70 wherein the needle 50 has a non-cutting piercing pencil point and an opening 53 for providing feedback. The [introducer] is slidably mounted on the needle and shorter than the needle in order for exposing the pencil tip of the needle. The first and second attachment was considered to be the structure which provides the friction fit. The force absorbing structure is considered the nose 65 of the catheter. Zohmann further discloses a central stylet 30 mounted in the needle."
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> (Office action, p. 4).

As discussed at the interview, the introducer of Zohmann is not "flexible" as required by applicants' claims. As disclosed at column 4, lines 24-26, Zohmann's "sharp, hollow introducer

component . . . is used to puncture the [patient's] skin", which could not be done with a flexible needle as required by applicants' claims. The introducer of Zohmann is "[inserted] at the puncture point", which could not be done with a flexible needle. (U.S. Patent 6,558,353 at column 2, line 39).

As described in applicants' Specification and discussed at the interview, a flexible needle is

> "characterized as a flexible conduit having distal and proximal ends. Preferred flexible needles have sufficient transverse flexibility to accommodate patient torso bending movement, whereby substantially to reduce a patient's awareness of the presence of the device. Flexible needles typically are made from medical grade plastic materials. For example, polyester shrink tube or similar materials may be used."
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> (Specification, underlining added, ¶ **[0018]**).

As further described in the Specification, applicant's flexible needle is made of catheter material and has sufficient transverse flexibility to deform, *i.e.*,

> **[0036]** [t]he outermost layer of the assembly 10 is the flexible needle 15 itself. It preferably is approximately 23 g and about the length of a conventional spinal needle, although different diameters and lengths for use with different procedures is within the scope of the present invention. Conventional plastic catheter material may be used in its construction. The flexible needle material may be reinforced with a flat ribbon internal spring 45 (shown in FIG.5), an internal or external wire wrap, or other reinforcing structure. Alternative materials, and various materials in combination, also may be used to construct a flexible needle 15. Suitable catheter material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from a patient. A flexible needle 15 desirably possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation from the presence of a foreign body.
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> (Specification, underlining added, ¶ **[0036]**).

Applicants have further added new claim 27, which recites the sufficient transverse flexibility features, and claim 28 which recites that the flexible needle comprises a medical grade plastic material, neither of which is disclosed by Zohmann.

In view of the foregoing, applicants request that the anticipation rejection be withdrawn.

F. 35 U.S.C. § 103:

Claims 5 and 21 were rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Zohmann in view of Kreuzer et al. (US Patent 5,116,323). Applicants respectfully traverse the rejection.

As discussed at the interview, Kreuzer does not remedy the inadequacy of Zohmann with respect to the "flexible needle" as required by applicants' claims. In view thereof, applicants request that the rejection be withdrawn.

The application should be in condition for allowance. If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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Date: January 30, 2007